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THE VALUE CLAIM PLATFORM: THE EVOLUTION OF OBJECTIVE KNOWLEDGE

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ABSTRACT

The evolution of objective knowledge over a health technology's lifecycle is vital to credible health technology assessment (HTA) and sustainable formulary decision-making. Traditional HTA models, typically anchored to a single reference-case cost-effectiveness claim, rely heavily on simulations, ordinal utility scores, and static assumptions; yielding claims that are neither testable nor reproducible across real-world contexts. This approach fails to meet the standards of normal science, lacks empirical verifiability, and undermines credible long-term decision support.

By contrast, a value-claim platform offers a dynamic, evidence-based framework for constructing progressive, evaluable, and replicable claims over the lifecycle of a therapeutic product. From launch, this platform anchors on well-defined compliance, the measurable adherence of patients to therapy, as the critical foundation. Building on compliance, the platform extends empirical claims to resource utilization, therapy switching, clinical outcomes, and patient-reported construct; each developed via protocols adhering to interval or ratio measurement standards, avoiding composite or ordinal metrics.

This structured, dynamic system enables real-world reproduction of pivotal trial findings, while accommodating shifts in population behaviors, treatment paradigms, and health system demands. It aligns with post-HTA reassessment trends seen in jurisdictions like Australia, where ongoing evaluation of technology performance and utilization is essential to timely and relevant reimbursement decisions. Importantly, the inclusion of Rasch-modeled patient-reported outcomes, such as need fulfillment, enables scientifically robust, unidimensional, and cross-culturally invariant measurement of subjective value, elevating the patient voice beyond anecdote.

The platform thus embodies a shift from static, simulation-based imaginary valuation toward a scientifically defensible, adaptable, and transparent structure of real-world evidence. It supports continuous dialogue between manufacturers and health systems, enhances formulary rigor, and aligns evaluation with normal scientific principles. In a landscape increasingly demanding empirical credibility and measurement fidelity, the value-claim platform provides a necessary alternative to outdated, pseudoscientific cost-effectiveness models. It offers a reproducible, evidence-driven pathway for assessing therapeutic value across time, settings, and evolving clinical realities.

INTRODUCTION

The evolution of objective knowledge regarding the comparative therapeutic effect of a product over its lifecycle is central to credible health technology assessment and long-term formulary decision-making [1]. Unlike the dominant model embraced by many health technology assessment agencies, which centers on a single-point-in-time reference case claim of cost-effectiveness, a credible value platform recognizes that knowledge evolves and must be continually updated in light of empirical evidence. The reference case model, built on simulation, assumptions, and ordinal utility scores, presents the illusion of precision while failing to meet the fundamental standards of normal science or the axioms of measurement theory. It generates imaginary claims that are not testable, not replicable, and not capable of empirical reassessment as a product moves from trial conditions to clinical practice. In contrast, the value claim platform offers a structured approach grounded in protocols that support predictive, evaluable, and replicable claims. It enables the progressive construction of knowledge about the actual therapeutic contribution of a product as it is used in defined populations under real-world conditions.

From the moment of product launch, the platform initiates a series of linked claims that are built upon clearly defined behaviors, such as compliance and therapy switching, and extend to clinical, resource, and patient-reported outcomes. These protocol driven claims are not frozen in time but can be updated, tested, and refined as data become available across different health system settings. This dynamic structure allows for the evaluation of comparative effectiveness as patients transition between therapies, as population profiles shift, and as broader treatment patterns evolve. It supports both reproduction of pivotal trial claims under modified protocols and real-world assessments that align with the decisionmaking needs of payers and providers.

Crucially, the platform accommodates health system imperatives such as periodic disease area or therapeutic class reviews. These reviews are often conducted to re-evaluate the positioning of products in the context of emerging evidence, changing standards of care, or budgetary considerations. A static cost-effectiveness model, frozen at launch and based on arbitrary thresholds, cannot respond meaningfully to such reviews. It lacks the empirical foundation to guide formulary adjustments, especially when confronted with newer products or shifts in clinical guidance. The platform, by contrast, supports a dynamic framework in which products can be compared within a shared evaluative structure. This permits the consistent application of protocols across a class of therapies, allowing for direct and meaningful comparison of claims related to compliance, switching behavior, resource impact, and subjective patient outcomes using Rasch-modeled instruments [2].

In this way, the platform does not merely support the launch of a product but embeds the product within a learning system. It recognizes that therapeutic value is not fully knowable at launch and must be built through evidence over time. The lifecycle perspective adopted by the platform enables manufacturers and health systems to engage in a dialogue grounded in evolving evidence, not abstract projections. It provides a scientific and measurement-based alternative to the pseudoscientific claims of costeffectiveness simulation, ensuring that decisions are based on what can be known, measured, and evaluated in the populations for whom therapies are intended.

OVERVIEW OF THE INITIAL PLATFORM

The development of a value claim platform is an essential step in presenting credible, evaluable, and replicable predictive claims for a new pharmaceutical product. Rather than approaching value claims as isolated or piecemeal assertions, a platform provides a structured, coherent framework that ensures each claim is meaningful, empirically grounded, and aligned with health system decision needs. This framework is anchored by a foundational claim: compliance. Without establishing the extent to which patients are actually taking the therapy as intended, all subsequent claims risk being irrelevant or misleading. Compliance, specifically defined in terms of medication possession or adherence behavior over an agreed-upon timeframe, is the entry point. It defines the population for whom value claims will be developed and tested. This approach rejects the notion that all patients initiated to therapy should be grouped together when assessing outcomes. Instead, only those who meet pre-defined compliance criteria qualify as the base population for predictive evaluations.

From this base, a series of linked claims can be developed, each of which depends on the foundation laid by the compliance definition. Resource utilization is a natural extension. Claims for reduced hospitalizations, emergency visits, or other forms of resource engagement only have credibility when they refer to patients who were compliant with the therapy. If compliance is not established, then observed utilization patterns cannot be reasonably attributed to the therapeutic effect of the product. Equally, such claims must focus on single, unidimensional resource types, avoiding the pitfalls of bundled or composite measures which obscure interpretation and violate measurement standards. The goal is to ensure that resource use claims are measurable on interval or ratio scales and reflect a linear relationship with outcomes of interest.

A further extension of the platform is a predictive claim around therapy switching. As a new product enters the market, it is important to understand the dynamics of uptake; how patients are switching from established therapies to the new option. This switching behavior is not only a measure of market penetration, but also has implications for health system planning and resource allocation. Capturing therapy switching in the context of the compliant patient population allows for an assessment of realworld displacement and preference, offering insight into the likely trajectory of adoption under formulary guidance or coverage policies.

At the same time, pivotal trial claims must be revisited. Rather than assuming trial results will be borne out in clinical practice, the platform encourages a reproduction or replication exercise using real-world data. This involves applying the same or modified trial protocols within the compliant population to assess whether outcomes are consistent. The platform, therefore, serves as a mechanism for confirming or qualifying the evidence base under actual use conditions, which is vital for health technology assessment and payer decision-making.

Finally, the platform allows for the incorporation of Rasch-modeled patient-reported outcome claims. These are not general satisfaction ratings or summary scores, but rigorously developed instruments that measure latent constructs such as confidence in therapy or perceived need fulfillment. These subjective value claims are evaluated using conjoint simultaneous measurement principles, yielding interval or ratio scale scores that meet the requirements of fundamental measurement. Positioned within the platform, these Rasch-based claims provide an essential dimension of product value, especially as patient-centered care becomes a guiding principle in formulary decision-making.

In sum, the value claim platform is a carefully organized, conditional framework where each claim builds on the foundation of compliance. It ensures that predictive claims are not only testable but logically and empirically connected. This structure provides clarity for manufacturers and decision-makers alike, allowing for transparent evaluation of the product's impact across clinical, behavioral, economic, and patient-centered domains.

THE COMMITMENT TO VALUE CLAIMS

The commitment to value claims is central to the integrity and scientific rigor of the value claim platform. It marks a departure from traditional approaches to health technology assessment that rely on fixed, unevaluable simulations and hypothetical scenarios detached from real-world evidence. In contrast, the platform supports the development of modeled value claims that are constructed with the explicit intention of empirical evaluation. These claims are not speculative forecasts but structured hypotheses that can be tested against observed data. They are designed to reflect the anticipated impact of a new product on key dimensions such as compliance behavior, resource utilization, therapy switching, and clinical outcomes in defined target populations.

The strength of this approach lies in its adherence to the principles of normal science. Models used to support value claims, whether regression-based or simulation-driven, must conform to standards of fundamental measurement. That is, they rely exclusively on inputs and generate outputs that are consistent with ratio or interval measurement properties. Each modeled claim must be supported by variables that meet the criteria for unidimensionality, linearity, and invariance. By maintaining measurement integrity, the platform ensures that value claims can be subjected to meaningful empirical evaluation. Claims that do not meet these standards, such as those built on ordinal utility scores or composite outcomes, are excluded, as they cannot produce outputs that support demarcation, replication, or falsification.

What distinguishes these modeled claims is that they are not static. They represent a commitment to ongoing assessment, where the initial assumptions and predictions are open to refinement as more data become available. As a product matures within its therapeutic area, the platform allows models to be recalibrated to reflect updated patterns of patient behavior, shifting clinical guidelines, or new treatment competitors. This adaptability is essential for supporting ongoing formulary reassessments, particularly in systems where coverage decisions are regularly reviewed in light of real-world evidence. The platform thus enables a continuous dialogue between manufacturers and health systems, grounded not in abstract projections but in evolving empirical evidence.

The commitment to value claims is also a commitment to transparency and scientific accountability. Each modeled claim must be backed by a protocol that specifies the data requirements, population definitions, measurement instruments, analytic techniques, and evaluation timeframe. The ability to replicate or reproduce the modeled claim in other settings or health systems is central to its credibility. The claim is not considered valid because it is plausible or aligns with clinical intuition; it is valid because it can be tested and either confirmed or rejected on the basis of observed outcomes.

In this way, the platform provides a structured environment in which all value claim, whether for anticipated compliance, expected resource use savings, projected therapy displacement, or real-world clinical effects, are developed with the goal of empirical verification. This ensures that the platform

remains a tool not only for market access at launch but for sustained, evidence-driven formulary support throughout the lifecycle of the product.

MAINTENANCE OF THE VALUE CLAIM PLATFORM

The long-term credibility and utility of the value claim platform depends on a structured commitment to its ongoing maintenance. A platform that supports predictive, evaluable, and replicable claims cannot be sustained passively; it requires continuous oversight, refinement, and updating to remain responsive to evolving evidence and health system requirements. This responsibility rests with the manufacturer. From the moment of launch and throughout the product's lifecycle, the manufacturer must take ownership of the platform as a dynamic scientific asset. Maintenance is not an optional or peripheral task, it is central to ensuring that the value claims remain relevant, defensible, and capable of guiding coverage, access, and formulary positioning.

To achieve this, the manufacturer must allocate appropriate resources, both financial and human, to a dedicated platform maintenance group. This group may be housed internally or supported through contracted external expertise, depending on the structure and capabilities of the organization. Regardless of configuration, the group must be trained in the scientific principles that underpin the platform, including fundamental measurement standards, the demarcation of empirical claims, and the modeling techniques used to generate evaluable value statements. The team must have a firm grasp of the platform's architecture, the protocols supporting individual claims, and the analytic methods used for replication, reproduction, and predictive model validation.

Training for the maintenance group should be ongoing and interdisciplinary. It must cover the technical aspects of data management and statistical modeling, the principles of Rasch measurement where subjective claims are included, and the operational frameworks used by health systems to conduct reviews and reassessments. Team members should be capable of interpreting emerging evidence in the therapeutic area and assessing its implications for existing value claims. They must also be prepared to revise, retire, or re-specify claims based on feedback from payers, regulators, and clinical practice trends. This requires not only technical skill but a mindset oriented toward continuous scientific engagement.

Contracting with external specialists for parts of the maintenance function may be appropriate where deep expertise in real-world data analytics, Rasch modeling, or therapeutic domain knowledge is required. These partnerships must be managed under clearly defined standards and expectations, ensuring that all contributions align with the platform's commitment to empirical credibility. Contractors should work under the same protocols that govern the internal team, with full transparency in model development, data interpretation, and claim revision procedures.

Platform maintenance is not merely about updating datasets or adjusting model coefficients. It is about sustaining the scientific integrity of the value claim structure and ensuring that each claim continues to meet the criteria of being credible, evaluable, and replicable. It means responding to health system reviews, evolving standards of care, new comparative evidence, and changes in target patient populations. The manufacturer's responsibility includes the anticipation of such developments and the readiness to adapt the platform accordingly. In doing so, the manufacturer upholds the central premise of the value claim platform: that claims must be grounded in science, open to scrutiny, and continually shaped by the best available evidence.

GLOBAL REACH OF THE PLATFORM

The value claim platform is not confined to a single jurisdiction or health system. Its structure, grounded in the principles of normal science and fundamental measurement, allows it to function as a global asset that can be adapted and applied across diverse healthcare environments. As a core evaluative framework, the platform offers a consistent approach to formulating and testing value claims, while remaining flexible enough to meet the varied evidentiary requirements and operational realities of regional and national health systems. For manufacturers operating across multiple markets, the platform becomes an essential tool for aligning global strategy with local decision-making needs.

Every health system brings its own set of challenges. Some maintain sophisticated, centralized data infrastructures with comprehensive patient-level records, while others operate in fragmented environments where data is sparse, inconsistent, or inaccessible. These differences affect the feasibility of testing certain claims, particularly those dependent on long-term outcomes, detailed switching histories, or Rasch-modeled patient-reported data. The platform is designed with this variability in mind. It provides a structure that regional and national product groups can access and tailor to their data environment, selecting from a suite of claims that are relevant and feasible for evaluation in their specific setting. It does not impose a rigid hierarchy of evidence but offers a modular system in which claims can be prioritized, adapted, and sequenced as appropriate.

By supporting this global reach, the platform also helps to ensure consistency in the communication of product value. While claims may differ in emphasis or availability from one health system to another, the underlying protocols remain standardized. This allows for internal alignment across product groups, reduces duplication of effort, and facilitates a shared understanding of how evidence is generated and interpreted. The platform becomes a living knowledge base that accumulates insights from each application, which can in turn inform future adaptations. If a particular predictive claim is evaluated in one country and refined based on those results, that learning can be transferred to other jurisdictions, improving the accuracy and relevance of similar claims elsewhere.

Maintaining this global coherence requires coordination. A central team responsible for overseeing the platform must work in collaboration with local product leads, ensuring that platform standards are upheld while allowing for the necessary contextual adaptations. This includes guidance on how to handle limitations in local data, whether through simplification of protocols, use of proxy measures, or staged implementation of claims over time. The goal is not to achieve uniformity for its own sake, but to ensure that wherever the platform is used, it continues to produce claims that are credible, evaluable, and replicable in the setting to which they are applied.

Ultimately, the global reach of the platform reinforces its role as a strategic asset. It equips manufacturers to respond not only to the regulatory and reimbursement requirements of individual health systems, but to the broader imperative of scientific accountability. In doing so, it bridges the gap between global product development and local evidence-based decision making, offering a unified yet adaptable structure for assessing therapeutic value across the product lifecycle.

THE MEASUREMENT IMPERATIVE

A key strength of the value claim platform is its ability to support the development and deployment of Rasch measurement instruments for the evaluation of latent patient-reported traits. Rasch modeling offers a uniquely robust framework for transforming ordinal responses into interval measures, enabling the assessment of unidimensional traits such as confidence in therapy, perceived convenience, or need fulfillment. What distinguishes Rasch from other approaches to patient-reported measurement is its invariance property; the capacity of a well-specified Rasch instrument to maintain its measurement structure across different populations and settings, provided that appropriate language versions are developed and validated. This makes Rasch-based claims particularly well-suited for global application and for consistent evaluation of the patient voice in diverse health systems.

Rasch in important because it is a model that enforces adherence to the axioms of fundamental measurement. It is the only model for developing instruments that meets the axioms of the representational theory of measurement first formalized in the late 1960s [3]. These axioms, the result of some 50 years of measurement theory development are absent in health technology assessment as it is presently practiced, but are central to any platform to support ongoing product reassessment [4]. These axioms cover both physical objects, the commitment to linear ratio measures with constant absolute differences as well as the logit measure of the Easch model to support claims based on constant relative differences.

In a landscape where subjective claims are often dismissed as unreliable or anecdotal, Rasch instruments offer a scientifically grounded means of capturing one of the most important yet elusive dimensions of therapeutic value: how patients perceive their therapy in relation to their own needs and expectations. Manufacturers may choose to focus on a single, well-defined latent trait, such as need fulfillment, as a core reference claim embedded in the platform. This enables a unified approach to measuring subjective value across different health systems. Each local version of the instrument can be adapted linguistically and culturally while preserving the mathematical integrity of the measurement structure. The result is that patient experiences can be meaningfully compared and evaluated across jurisdictions using a consistent, valid, and replicable framework.

The incorporation of Rasch-modeled need fulfillment as a standard value claim is particularly compelling in therapeutic areas where treatment goals are not solely defined by clinical outcomes but also by how well a therapy aligns with patient priorities. Whether the issue is ease of administration, symptom relief, quality of daily functioning, or emotional reassurance, the Rasch approach allows these dimensions to be systematically assessed, quantified, and incorporated into the broader value narrative of a product. The platform thus brings methodological rigor to the incorporation of the patient voice, offering an empirically credible alternative to generic satisfaction surveys or ad hoc qualitative findings.

Moreover, the existence of a scientifically structured platform with embedded Rasch instruments gives the manufacturer a strong foundation for engaging with health systems that continue to rely on reference case cost-effectiveness models. These models, based on ordinal utility scores and imaginary simulation projections, lack empirical credibility and fail to meet the minimum standards of measurement required for scientific assessment. The platform allows the manufacturer to argue from a position of evidencebased integrity, advising that such reference case approaches be reconsidered in favor of value claims that can be tested, replicated, and aligned with real-world experience. The ability to offer

consistent, Rasch-modeled assessments of a central patient-centered construct such as need fulfillment across countries further strengthens the manufacturer's case for rejecting imaginary cost-effectiveness outputs in favor of empirical claims that reflect what patients actually experience when they engage with a new therapy.

In this way, the Rasch measurement component of the platform is not merely an add-on but a core asset. It provides the means to support scientifically valid, globally consistent subjective value claims that reinforce the overall credibility of the platform and enable meaningful comparisons of patient response across health systems.

CONCLUSIONS

To date, meeting the formulary submission requirements for new therapies has been remarkably simple and, in many ways, scientifically superficial. For decades, the prevailing reference case approach, exemplified by the practices of the Institute for Clinical and Economic Review and similar agencies, has relied on a narrow yet flawed framework. The typical submission includes two core components. The first is a series of indirect claims, most often derived from pivotal clinical trials. These trials frequently lack robust or relevant comparator therapies and offer only limited insight into how the product will perform in actual health system settings. These claims are based on highly controlled environments that do not reflect real-world complexities, rendering any assertion of therapeutic superiority or value highly conditional and of questionable relevance.

The second component, which has come to dominate formulary assessments, is the reference case costeffectiveness simulation model. These models operate by projecting long-term outcomes and costs based on a series of assumptions, many of which are speculative, unverifiable, and dependent on ordinal utility scores that do not meet the basic criteria of fundamental measurement. The simulations often extend far beyond the timeframe of any empirical observation, with modelers filling in gaps with preference scores, transition probabilities, and utility estimates that cannot be directly tested. These models give the appearance of scientific rigor, but they are, in essence, elaborate exercises in numerical storytelling. There is no empirical standard by which the outputs of such models can be evaluated or falsified. Once the model is constructed and the simulation run, the analysis is considered complete. That, in most submissions, is the end of the story.

The reference case model, is , to be charitable, totally inadequate as a foundation for informed decisionmaking. It fails to recognize the essential role of interval or ratio-scale claims and the necessity of fundamental measurement for any value assertion to be evaluable. For a claim to be credible and serve as the basis for reimbursement or formulary placement, it must be capable of being tested, replicated and, if necessary, refuted. This is the standard that underpins all scientific inquiry and it is precisely what the current HTA belief system ignores; or unaware. Instead, the focus remains on constructing models that generate outputs which cannot be verified, grounded in assumptions that are often hidden from scrutiny, and justified by metrics that lack mathematical legitimacy.

This has been the dominant standard in health technology assessment for over forty years. The question now is whether practitioners will continue to operate within this comfort zone of limited comparative clinical assessment outside of high constrained trial protocols and pseudoscientific simulation modeling or whether there will be a serious effort to embrace the principles of normal science. This requires a shift

in thinking, from imaginary projections to empirical evaluation, from ordinal scoring to interval and ratio measurement, from speculative claims to ones that are evidence-based and testable in real-world settings.

The value claim platform offers the only credible path forward. It rejects the idea that imaginary costeffectiveness claims are sufficient and instead insists on a structure in which every claim is developed through a defined protocol, evaluated with real data, and held to the standards of scientific replicability. It accommodates predictive models, but only those constructed with valid inputs and designed to yield outputs that meet the criteria of meaningful measurement. It recognizes that real-world decision-makers need more than simulations, they need structured, credible evidence on compliance, resource use, switching behavior, clinical outcomes, and patient-reported experiences, each of which must be framed within protocols that meet the standards of normal science.

In an environment where scientific rigor is increasingly demanded, continuing to rely on outdated, unverifiable methods is no longer defensible. The choice for HTA practitioners is clear: continue with the fiction of cost-effectiveness reference case modeling, or adopt a framework that is committed to the creation and evaluation of real, measurable value. The value claim platform is not just an alternative; it is the necessary response to decades of methodological complacency.

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